February 11, 2000

Summary Notes of Discussion
Radiological Health Reengineering Meeting

Scheduled for January 25-26, 2000
The Food and Drug Law Institute
1000 Vermont Ave. NW, Suite 200
Washington, DC 20005

Background

The Food and Drug Administration's Center for Devices and Radiological Health (CDRH) was formed in 1982 from the merger of two Bureaus, the Bureau of Medical Devices and the Bureau of Radiological Health. Radiological health activities have been an important part of the Center's (and its predecessor organizations' public health and regulatory responsibilities for many years. However, resources devoted to these activities have declined significantly since 1982. The Center is presently engaged in a long-term process of analyzing its radiological health responsibilities in terms of these resource exigencies, with the intention of making important programmatic and strategic decisions regarding the program.

At the request of CDRH, The Food and Drug Law Institute (FDLI) invited a number of organizations to nominate representatives to attend a special meeting. The organizations contacted, including private sector organizations and government agencies, were those known to have a programmatic interest and expertise in the subject of radiological health. The purpose of the meeting was to garner the opinions of the participants about the overall issue of the incompatibility between CDRH's radiological health responsibilities and its resources. The meeting was originally scheduled to take place over two days, Tuesday and Wednesday, January 25-26, 2000.

Due to an unexpected snow storm, many participants were unable to make the meeting on Tuesday, January 25, so the meeting was rescheduled for the following day, Wednesday, January 26. Although a number of expected participants were even unable to attend the Wednesday meeting due to the bad weather, there were a total of 17 people who did attend on Wednesday. At the end of this report is a list of participants and a list of those expected to attend who could not. The meeting was held from approximately 9 AM to nearly 4 PM.

The meeting was facilitated by Joseph S. Arcarese, Executive Vice President, FDLI. This summary was prepared from his notes, and a draft was circulated to meeting participants for their review and comment. Revisions to the draft were made and this document is the outcome of that process. One participant, James Camburn, Chief of the Radiation Safety Section of the Michigan Department of Consumer & Industry Services, offered two additional documents in support of the overall purpose of the meeting, and files of those documents are available and have been distributed electronically along with the electronic transmission of this document.

Meeting Summary

After a welcome by Joe Arcarese, the participants were asked to introduce themselves and to give a brief description of their experience with and interest in radiological health. Then Joanne Barron, Radiological Health Reengineering Team Leader for CDRH, gave a slide presentation of the radiological health reengineering program and the results to date of the work of the reengineering team. A file of her Powerpoint slides is available and has been distributed electronically along with the electronic transmission of this document.. After her presentation, there was an open-ended discussion among all the participants. This document presents notes summarizing comments made by the participants throughout the meeting. There was no attempt to reach any consensus on any matter nor were any reached. The main point of the meeting was to offer CDRH an opportunity to hear the opinions and comments of the invited participants about the relative importance of various radiological health program activities in light of severe resource restrictions.

Comments made by participants:

1. CDRH should emphasize the accomplishments of its radiological health program in the past, and should discuss the benefits to the public of the program's accomplishments. The current radiological health reengineering effort should be discussed in that context of accomplishments and benefits.

2. CDRH should communicate information to the public about the radiological health program accomplishments and the reengineering efforts.

3. The slide presentation made by Joanne Barron was congratulated by many participants as being an excellent summary and analysis. However, many participants had difficulty with Slide 33. They found it confusing and misleading. They said that it doesn't demonstrate the real benefits of the radiological health program. Instead, they suggested the need for data to prioritize the real public health problems posed by various radiation-emitting technologies, including patterns of use, exposures, and the epidemiology of those exposures. Relating to their confusion was a question about the real potential public health problem posed by color televisions. Joanne mentioned, in answer to a question about whether there are significant radiological health problems from the CDRH perspective, that some new products (especially a proliferation of new kinds of laser products) present new and unique risk problems, as well as off-shore products produced by manufacturers without a strong awareness of radiological health requirements, and the general lack of knowledge of radiation safety by users.

4. CDRH ought to have outreach with other relevant government and private sector organizations at the top of its priorities, because it has lost much of its internal expertise, and because many organizations no longer know the Center like they used to.

5. Manufacturing of radiation-emitting products, such as medical radiation equipment, is a world-wide industry, and there is a need for global partnerships. Manufacturers have an increasing interest in global harmonization. It is frustrating to them that each national authority wants to regulate the industry, without harmonizing and partnering with the regulatory authorities

of other countries. Consequently, this leads to expensive duplication of effort on the part of the manufacturers who wish to trade in different countries. What is needed is an emphasis on harmonization, mutual recognition agreements, partnering, leveraging on a world-wide scale. There was a recommendation that CDRH partner with the Diagnostic Imaging and Therapy Trade Association, in order to work out common interests and concerns, and to work cooperatively in the development of standards for global applicability. It was also recommended that CDRH work with the International Radiation Protection Association (IRPA).

6. Concerns were expressed about the loss of CDRH's world-wide leadership in radiation protection, especially its public health leadership. For example, participants questioned who was looking at the overall public health benefit/risk balance with the people scanner technology. It was noted that coordination was lacking among all the Federal agencies with radiation mandates, and that the loss of CDRH expertise and resources diminished its ability to function effectively amid all these other agencies. Representatives from the Environmental Protection Agency (EPA) and the National Institute for Occupational Safety and Health (NIOSH) mentioned their own loss of resources and expertise in radiation, and their reliance on CDRH due to its broad mandate under the Radiation Control for Health and Safety Act (RCHSA).

7. There were comments about the overlapping requirements for certain electronic radiation emitting products that are also medical devices, and the question about whether the overlaps can be eliminated. The overlap areas mentioned were incident and corrective action reporting.

8. A strong thematic element throughout the meeting was the question, what <u>is</u> the demonstrable public health benefit of the radiological health program to date (i.e., where are the "dead bodies"?). Certainly there are radiation protection success stories with obvious impact, such as the microwave oven standard that has prevented the potential for serious eye injuries due to malfunctioning ovens from ever becoming actualized. But a successful radiation protection program that has prevented radiological injuries might now be the victim of its own success, in that "dead bodies" aren't and haven't been apparent (whereas they do occur with distressing regularity in the medical device world). It is difficult to prove that the possible detriments from excess radiation exposure would have occurred if the radiation protection program had not been successful (i.e., that "dead bodies" aren't apparent now because the radiological health program has prevented them from happening). However, as was suggested by one participant, the question about the necessity of the radiation program, along with the apparent lack of "dead bodies", needs to be reconciled at the FDA level.

The public perception about the ill-effects of radiation exposure may not agree with the science, and there may be a need to have a credible assurance to the public that unnecessary radiation exposure is being reduced. Also, there is an argument to be made that misuse of medical radiation (e.g., poor or inadequate diagnostic imaging or radiation therapy) may be equated to ill health and poor medical care. CDRH must make clear what the current problems are (e.g., laser pointers, people scanners, erythema from fluoroscopy, etc.) and to cut programs for

former problems (e.g., color television x-ray exposure[1]) that have presumably been solved. CDRH must also figure out how and to whom must it convey information about the current radiological health problems.

CDRH staff expressed their own discomfort about abandoning certain program areas, such as ionizing radiation protection activities, without knowing who else would do them. They wondered if they ought to abandon them anyway, even if there is no one else to pick up the ball, under the theory that enough has already been done in various aspects of ionizing radiation protection.

Both in the states and in Federal Agencies, radiological health activities must compete with other needs, and the question always boils down to how many lives are being saved, versus the resource expenditure. Especially when radiological health programs are aimed at reducing small amounts of unnecessary radiation exposure, the benefit/risk equation does not appear very favorable in comparison to the benefit/risk equation of other kinds of public health programs. Nevertheless, it was acknowledged that when the public discovers that CDRH (or presumably other regulatory agencies) are not performing the radiation protection activities that the public presumes are being done (e.g., inspecting newly manufactured equipment to assure that there is no excess radiation leakage), there could be public frustration, disappointment, and even outrage. This raises the question about what does the public presume is being done, and what are the public/press expectations for assurance of safety.

9. There was additional discussion of the "outrage" factor in dealing with the public concerning certain new technologies. Although CDRH is good at communicating with the press about technical matters, perhaps it is not as effective in communicating with the public (and within the political establishment) about issues in a way that resonates with the way that the public perceives them, and that communication deficiency only raises the risk of public outrage. The people scanner was mentioned as a "poster child" example of this phenomenon. It is technically correct to tell the public that the absolute radiation doses (in microrads) is insignificant. However, if the public's concern is about the very idea of scanning individuals in such a way that anatomical features can be observed, then the typical "technical" response provides little or no consolation, and public outrage may ensue.

10. There were comments that, if a performance standard for people scanners were developed, it might legitimize the use of this technology in all sorts of ways that convey no apparent benefit to the people scanned, e.g., scanning workers to uncover on-the-job theft. On the other hand, a standard could place an upper limit on allowable exposures, preventing exposure "creep" as is apparently occurring.

[1] Some participants were puzzled over CDRH staff assertions that color television x-ray exposure is still a potential problem, when the prevailing assumption is that modern technologies have eliminated the problem. If indeed a credible potential problem does still exist, then CDRH should make the case clear.

11. Another commenter pointed out that it is not always possible for CDRH to develop performance standards. But CDRH could facilitate meetings with appropriate organizations in order to develop consensus statements. The EPA representative mentioned the old Federal Radiation Council authority that EPA inherited when it was founded in 1970, that authorizes it to issue Federal Guidance relating to radiation. Mention was also made of ISCORS (Interagency Steering Committee on Radiation Standards), a current Federal interagency committee designed to increase coordination between Federal agencies with radiation authority, but squabbling among members is making this committee ineffective.

12. One participant felt that, within CDRH, priority should be given to its providing expertise, guidance, the benefit of its experience, and an Information Clearinghouse.

13. Another participant mentioned that, just as industry must constantly reevaluate its priorities in the face of rapid technological change, so too should CDRH frequently reevaluate its priorities. For example, instead of developing its own standards, CDRH ought to participate in international standards activities, and use international standards to fulfill its requirements. However, as it was pointed ought, severe travel budget limitations prevent sufficient CDRH participation on many international standards bodies. Although CDRH was encouraged to try to participate in other ways such as use of the videophone, another participant pointed out that there is no substitute to personal face-to-face interaction in order to foster successful collaboration with national and international organizations. The leveraging aspirations of CDRH won't work without this personal involvement.

14. It was pointed out that CDRH is also a "cop," and that occasionally it is necessary for the Center to exercise its enforcement muscle. However, CDRH has been remarkably effective over the years in convincing manufacturers and others to do the right thing regarding equipment coming under RCHSA, without having to be too heavy handed in implementing its coercive authority. Most companies have been willing to work to solve problems, once CDRH has made it clear to them what the problems are. Since the civil penalties that CDRH can level are still capped at $1000, and courts are unwilling to take these cases with such paltry amounts at stake, it is fortunate that CDRH is so effective at achieving voluntary compliance.

Along this same line of reasoning, one participant advocated that there is a continuing need for a CDRH, if only to keep things on an even keel. But CDRH needs to participate in global harmonization activities. There was also the recommendation that CDRH maintain an active (as opposed to static) list of ten priorities, that is used to help focus resources. There was a recommendation that CDRH keep the higher levels of HHS informed about radiological health, and to request information from them about matters of mutual concern.

15. The importance of having a technical training program for state and federal agencies and others was pointed out, as a means of keeping the supply refreshed of people trained in radiological health, and as a means of forging cooperative alliances and information exchange between CDRH and other organizations.

Joanne Barron asked for the opinions of the participants concerning the elements they would design into an electronic product radiation program, if they were starting one up fresh from the ground up. The following are suggestions of individual participants (note: they do not represent consensus):

1. CDRH should allow manufacturers to self-certify their compliance with national and international voluntary standards, as an acceptable substitute for certification with federal performance standards. However, it was recognized that the voluntary standards currently available have not all been developed in an open process, and not all assure safety. It was recommended that CDRH needs to maintain an active presence as standards are being developed, to assure that the public health aspects are being considered. CDRH would also have to acknowledge which voluntary standards it felt were acceptable (in keeping with a provision of the Food and Drug Administration Modernization Act [FDAMA]).

2. There needs to be a group within CDRH to determine the risk/benefit of various issues/products, and to determine appropriate priorities. This group should be on top of emerging products that may become problems, especially by talking to states, international standards organizations, and others who may be dealing with these problems. A related matter is whether the current list of products that occupy CDRH's attention include any (e.g., laser printers) for which CDRH need not be concerned? It was pointed out in this regard that Customs tariff codes don't match with CDRH's list of concerns, and that CDRH needs to meet with Customs and ORA to work this out.

3. There needs to be a visible indication (label) on manufactured products that indicates they comply with the provisions of the standard for which their manufacturer self-certifies.

4. There needs to be a program of user information, user training, and public information.

5. There needs to be a training program for states, FDA, other government agencies, and end users. As an alternative to CDRH having its own in-house training capability, one participant suggested that outside contractors could perform this training. However, it was pointed out that having an in-house training program helps develop in-house expertise (i.e., nothing helps develop expertise faster than having to teach someone else), and it builds trusting, communicative relationships between those taught and those doing the teaching, that has tremendous downstream impact on the success of the radiological health program.

6. CDRH needs to maintain an active collaboration with health professional organizations, trade associations, other Federal agencies, and other relevant non-government organizations. It was pointed out that FDA's former Office of Health Affairs was a good means of communicating with health professional organizations especially through face-to-face meetings with their Washington representatives.

Regarding coordination with other Federal agencies with radiation responsibilities, ISCORS was again mentioned as a venue. However, due to interagency disagreements, it was pointed out that ISCORS is not being effective. It was also pointed out that coordination needs to occur at the Center Director or Deputy Center Director level, as well as the technical/scientific level. Both levels are useful for collaborating.

7. CDRH needs to maintain its scientific expertise, and that some form of active research might be necessary in order to do that. However, it was also recognized that training and risk assessment activities will help maintain a level of credibility in scientific expertise.

8. CDRH needs to reanalyze all its requirements for manufacturer reporting. It was recommended that CDRH consider what crucial information it actually needs and intends to act on, in order to remove any duplicative or unnecessary information requirements.

9. Products and facilities on the market in compliance with RCHSA need to be labeled as complying, so that consumers have something positive that they can look for. This is not unlike the facility accreditation required by the Mammography Quality Standards Act (MQSA), in which facilities must display a certificate prominently for consumers to see. It was pointed out that the American College of Radiology (ACR) is currently developing some kind of "ACR stamp of approval."

10. CDRH needs to investigate the feasibility of a program of "third party certification" for compliance with RCHSA, where independent laboratories could test for compliance, in lieu of initial reporting. These laboratories (i.e., third party certifiers) would check for compliance with acceptable and applicable national and international standards.

In order to get such a program implemented, CDRH should meet with relevant trade associations to see their level of interest. If they are interested, then CDRH should assess the interest, capabilities, and expertise of potential accreditation laboratories, much as it has done regarding third party reviews of 510(k)s.

11. CDRH ought to maintain some measurement of population exposures (e.g., through NEXT [Nationwide Evaluation of X-ray Trends]), in order to obtain information needed to make risk estimations.

This concludes the discussions at the meeting. Below is a list of those who did attend the meeting, and a list of those who were scheduled to attend but did not due to weather-related problems or other reasons. A Powerpoint 2000 file of Joanne Barron's presentation and two Word files of Jim Camburn's documents are available as separate files.

List of Participants at the Meeting

Arcarese, Joseph S.
Executive Vice President (Meeting Facilitator)
Food and Drug Law Institute (FDLI)

Barron, Joanne
Regulatory Operations Officer (Team Leader: Radiological Health Reengineering Team)
Center for Devices and Radiological Health

Boyd, Mike
Health Physicist
Environmental Protection Agency

Butler, Penny
Director, Breast Imaging Accreditation Programs
American College of Radiology

Camburn, James F.
Chief, Radiation Safety Section, BHS
Michigan Dept. of Consumer & Industry Services
Representing: CRCPD

Collins, Belinda
Regional Radiological Health Representative
ORA/Food and Drug Administration

Frappaolo, Philip J.
Deputy Director, Office of Compliance
Center for Devices and Radiological Health

Gutberlet, Michelle
Executive Director
Electromagnetic Energy Association

Hallisey, Robert M.
Director, Radiation Control Program
Massachusetts Department of Public Health
Representing: CRCPD

Kroger, Larry
Senior Regulatory Programs Manager
Global Compliance & Regulatory Affairs
GE Medical Systems
Representing: NEMA

Linton, Otha
Consultant
Conference of Radiation Control Program Directors
Representing: CRCPD

Lotz, Greg
Chief, Physical Effects Branch
National Institute for Occupational Safety and Health

Mills, William
Member
Health Physics Society

Nishikawa, Robert M.
Assistant Professor
Department of Radiology (MC-2026).
University of Chicago

Rensberger, Judith
Senior Program Officer
Biomedical and Clinical Research Unit
Institute of Medicine
Representing: IOM/NAS

Suleiman, Orhan
Chief, Radiation Branch
Office of Health & Industry Programs
Center for Devices and Radiological Health

Villforth, John C.
President
FDLI

List of Those Previously Scheduled to Attend Who Did Not Attend Due to Weather Problems or Other Reasons

Ayres, Robert
Health Physicist
Materials Safety Branch
Office of Nuclear Materials Safety and Safeguards
Nuclear Regulatory Commission

Beckner, William M.
Executive Director
National Council on Radiation Protection
and Measurements

Britain, Robert
Vice President, Medical Products
National Electrical Manufacturers Association

Charp, Paul
Senior Health Physicist
Div. Health Assessment & Consultation
Agency for Toxic Substances and Disease Registry

Cummings, Kelly
Assistant Director
Electromagnetic Energy Association

Hickey, John
Chief, Materials Safety Branch
Office of Nuclear Materials Safety and Safeguards
Nuclear Regulatory Commission

Jacobson, Elizabeth
Deputy Director for Science
Center for Devices and Radiological Health

Jaeger, Robert J.
Program Officer
National Institute on Disability and Rehabilitation Research
U.S. Department of Education
Representing: IEEE

Kay, Brett
Program Associate
National Consumers League

Keys, David
Radiation Oncology Department
Deaconess Hospital
Representing: AAPM

Maidment, Andrew
Medical Physicist
Radiology Department, Thomas Jefferson University Hospital
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Mock, Tom
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The Consumer Electronics Association